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EMC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA *ex rel.* JAYDEEN VICENTE and JAYDEEN VICENTE Individually,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No.

NOTICE OF REMOVAL

TO THE CLERK OF THE ABOVE-ENTITLED COURT:

PLEASE TAKE NOTICE that defendant Eli Lilly and Company, Inc. ("Lilly") hereby removes to this Court the above-captioned case, originally filed in the Superior Court of California in and for the City and County of San Francisco, on federal question grounds pursuant to 28 U.S.C. §§ 1331, § 1367, and 1441(b).

As explained in detail below, this Court has original jurisdiction under 28 U.S.C. § 1331 in this case because Plaintiffs expressly allege violations of, and "liability under," the federal False Claims Act, 31 U.S.C § 3729. *See* Compl. ¶¶ 64, 210-211 & p.43. In addition, and independent of Plaintiffs' claims under the federal False Claims Act, this Court also has jurisdiction of Plaintiffs' state law claims for violation of the California False Claims Act under 28 U.S.C. § 1331 because those claims "necessarily depend[] on resolution of a substantial question of federal law." *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983); *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005).

In support of removal, Lilly states as follows:

1. This action was originally filed on May 11, 2007 *under seal* in the Superior Court of the State of California in and for the City and County of San Francisco, captioned as *State of California ex. rel. Jaydeen Vicente and Jadeen Vicente Individually, Plaintiffs, v. Eli Lilly and Company, Defendant*, Case Number CGC-07-463338.

2. On July 10, 2007, the State of California declined to intervene in this action.

3. Plaintiffs served Lilly with a copy of the Complaint and Summons on August 22, 2007. This Notice of Removal is timely, having been filed within thirty (30) days of service. *See* 28 U.S.C. § 1446(b).

4. This action involves allegations regarding the FDA-approved medicine Zyprexa®, which allegations are also made in multidistrict litigation captioned *In re Zyprexa Products Liability Litigation,* MDL No. 1596, pending before the Honorable Jack B. Weinstein in the United States District Court for the Eastern District of New York. Similar Zyprexa-related suits against Lilly by several States are already pending in MDL No. 1596.

5. Lilly intends to file shortly a Motion to Stay All Proceedings Pending Transfer by the Judicial Panel on Multidistrict Litigation ("JPML"), asking this Court to stay this action pending its transfer to MDL No. 1596. A stay will conserve the Court's and the parties' resources and prevent inconsistent rulings on global issues that arise repeatedly in actions involving Zyprexa. For this reason, courts in more than 100 other cases have granted stays pending transfer of Zyprexa-related actions to MDL No. 1596

6. True and correct copies of the Civil Case Cover Sheet, Proof of Service of Summons, State of California's Notice of Election to Decline Intervention Pursuant to Government Code Section 12652(c)(8)(D)(ii), Confidential Cover Sheet – False Claims Action, Civil Case Cover Sheet, Notice to Plaintiff of Case Management Conference, Stipulation to Alternative Dispute Resolution, and Judicial Mediation Program and Alternative Dispute Resolution (ADR) Information Package, Service of Process Summary Transmittal Form, Confidential Cover Sheet – False Claims Action, Proof of Service of Relators' Statement on the Office of the Attorney General in Sacramento, Proof of Service of Relators' Statement on the Office of the Attorney General in San Francisco, Proof of Service of Complaint For Damages [Under Seal]; Civil Case Cover Sheet; Confidential Cover Sheet – False Claims Action; Confidential Cover Sheet – False Claims Action on the Office of the Attorney General in Sacramento, and Complaint for Damages served on Lilly are attached hereto as Exhibit A. Exhibit A constitutes all process, pleadings or orders served on Lilly as of the date of filing this Notice of Removal.

7. Lilly will be filing a true and correct copy of this Notice of Removal with the Superior Court of California in and for the City and County of San Francisco and will serve the same on all parties of record pursuant to 28 U.S.C. § 1446(d).

THE COMPLAINT

8. Plaintiffs' Complaint alleges that Lilly illegally promoted the drug Zyprexa® for indications not approved by the United States Food and Drug Administration ("FDA") in violation of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), and federal regulations promulgated thereunder. *See, e.g.*, Compl. ¶¶ 37-51, 54-63.

9. The Complaint further alleges that Lilly violated the federal Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320, *et seq.* ("AKS"), by allegedly paying to physicians "illegal remuneration" in the forms of "'speaker fees,' honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa" to patients. Compl. ¶¶ 198 (p. 40, 42)[1], 192-201 (pp. 38-40), 202-211 (pp. 43-44).[2]

10. Plaintiffs surmise that, a result of Lilly's alleged violations of *federal* law – including Lilly's alleged "off-label" promotion of Zyprexa in violation of the FDCA and its alleged illegal payments to physicians and others in violation of AKS – false claims for reimbursement were submitted to *both* the federal Medicare and state Medicaid programs. *See, e.g.,* Compl. ¶ 50 (alleging that numerous allegedly false claims were submitted to the "Medicaid/Medicare programs for reimbursement").

11. According to Plaintiffs' Complaint, these claims were "false" because *federal law* precluded reimbursement of claims that did not meet the federal definition of "covered outpatient drug" and each of the individual uses for which the drug was prescribed (and a claim for reimbursement submitted) was not "approved by the FDA, or supported by one of the three specifically identified compendia." Compl. ¶ 39 (citing 42 U.S.C.A. §§ 1396r-8, 1396(k)(3), 1396(k)(6) & 1396(g)(1)(b)(i)). Plaintiffs contend that the alleged submission of these claims that were not eligible for reimbursement constitutes "**[p]redicate Acts Giving Rise to Liability Under the State and Federal False Claim Acts**." Compl. at p.43 (underline added, bold in original).

12. Based on these allegations (which are incorporated by reference in each of Plaintiffs' Causes of Action), the Complaint purports to allege the following four counts, entitled: (1) First Cause of Action, California False Claims Act, California Government code § 12650 et seq.; (2) Second Cause of Action, Conspiracy to Submit False Claims in Violation of the California False Claims Act, California Government Code § 12651(a)(3); (3) Third Cause of Action, Violation of

[1] The Complaint contains two different versions of paragraphs 194-208 (pp. 39-44). Citations to both paragraph and page therefore have been included where necessary to eliminate any confusion.

[2] Lilly denies all of Plaintiffs' allegations of wrongdoing.

Business & Professions Code § 17200; and (4) Fourth Cause of Action, Violation of Business & Professions Code § 17500.

13. Plaintiffs seek treble damages, civil penalties and fines, attorney fees, and costs of suit.

FEDERAL QUESTION JURISDICTION

A. This Court Has Original Jurisdiction Over Plaintiffs' Federal False Claims Act Claims

14. Title 28 U.S.C. § 1441(b) provides in pertinent part:

> Any civil action of which the district courts have original jurisdiction founded on a claim or right arising under the constitution, treaties or laws of the United States shall be removable without regard to the citizenship or residence of the parties.

15. Although Plaintiffs have artfully avoided enumerating or captioning their federal False Claims Act allegations as one of their four Causes of Action, Plaintiffs' Complaint expressly alleges liability under the federal False Claims Act. *See* Compl. at p. 43 (alleging that Lilly is liable "[u]nder the State and Federal False Claim Acts") (emphasis added); ¶ 210 (alleging "Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act . . . .") (emphasis added); ¶ 211 (alleging "Lilly's conduct is also punishable under . . . the Federal False Claims Act") (emphasis added); ¶ 64 (citing federal False Claims Act).[3]

16. Because Plaintiffs expressly allege violations of the federal False Claims Act, this Court has federal question jurisdiction over those claims, and Plaintiffs' entire Complaint is properly removable to this Court. *See* 28 U.S.C. § 1367 (providing supplemental jurisdiction over all related state law claims).

[3] The fact that Plaintiffs' federal False Claims Act claims are procedurally improper or wholly without merit does not defeat removal jurisdiction. *See* Schwarzer, Tashima & Wagstaffe, California Practice Guide – Federal Civil Procedure Before Trial §2:700 at 2D-48 (The Rutter Group 2007) ("If plaintiff is asserting a federal claim (whether or not meritorious), defendant has the right to a federal forum. Removal is therefore proper even if plaintiff's federal claim is meritless") (citing *Barraclough v. ADP Automotive Claims Services*, 818 F. Supp. 1310, 1312 (N.D. Cal. 1993) ("A plaintiff should not be permitted to effectuate remand by pointing out the flaws in her own compliant, in effect arguing for dismissal of that claim.")).

B. Plaintiffs' California False Claims Act Allegations Necessarily Depend on Resolution of Disputed and Substantial Federal Questions

17. Independent of Plaintiffs' federal False Claims Act claims, this Court also has federal-question jurisdiction over Plaintiffs' state law Claims for violation of the California False Claims Act (the First and Second Causes of Action) under 28 U.S.C. § 1331 and the principles set forth in *Grable*, 545 U.S. 308.

18. The United States Supreme Court's decision in *Grable* held that federal question jurisdiction did not require the plaintiff to have asserted a violation of a federal statute providing a private parallel right of action.[4] Rather, under *Grable*, a case asserting only state law causes of action is removable if it raises a substantial federal question, "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." *See Grable,* 545 U.S. at 314-320.

19. As more fully explained below, Plaintiffs' claims require construction and application of three areas of federal law: (1) the FDCA, 21 U.S.C. § 301, *et seq.* and implementing federal regulations which govern approval of new drugs and regulate prescription drug manufacturers' promotional statements, including all aspects of warnings in labeling and advertising; (2) the federal Medicare and Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320, *et seq.* ("AKS"), which prohibits certain remuneration with respect to the sale of prescription drugs; and (3) federal Medicaid law, which determines the drugs for which a State can decline to pay, *see* 42 U.S.C. §§ 1396r-8(d)(B), (d)(4).

20. In *In re Zyprexa Prod. Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005), the federal court held that it had federal question jurisdiction over virtually identical state law claims by Louisiana involving Lilly's marketing of Zyprexa and Louisiana's payments for Zyprexa and under its Medicaid program. The court found that references in the complaint to federal funding provisions and laws and allegations related to marketing for non-FDA approved uses demonstrate "a core of

[4] *Grable* limited *Merrell Dow Pharmaceuticals Inc. v. Thompson,* 478 U.S. 804 (1986), to the extent *Merrell Dow* implied or held that a federal cause of action was required to remove a pharmaceutical product liability case.

substantial issues" that were federally oriented. *Id. at 172-73; see also West Virginia v. Eli Lilly and Company,* 476 F. Supp. 2d 230 (E.D.N.Y. 2007) (denying motion to remand in action by Mississippi involving substantially same allegations).

21. Similarly, in a case involving Medicaid drug pricing, this Court in *County of Santa Clara v. Astra USA, Inc.*, 401 F. Supp. 2d 1022 (N.D. Cal. 2005) invoked federal question jurisdiction under *Grable* because the plaintiff's state law claims against pharmaceutical manufacturers for allegedly overcharging plaintiff for Medicaid drugs presented substantial questions of federal law. *Id.* at 1031. In concluding that Medicaid drug pricing issues merited federal jurisdiction, the court observed that one measure of evaluating substantiality is "the importance of the federal issue." *Id.* at 1027. The court noted that "[u]nder this approach, the following issues have been found to be substantial: those that directly affect the functioning of the federal government, those in an area reserved for exclusive federal jurisdiction, and those that impact a complex federal regulatory scheme." *Id.*

22. Because Plaintiffs' claims in this case, like those in *Grable, In re Zyprexa, West Virginia* and *County of Santa Clara*,[5] will necessarily involve the resolution of disputed and substantial federal questions in the context of three complex and inter-related federal regulatory schemes, this Court has federal question jurisdiction

1. Plaintiffs' Right to Relief Requires Resolution of Disputed and Substantial Issues Under the FDCA

23. At the heart of this case are claims based on alleged violations of the FDCA by Lilly, in particular, that Lilly illegally promoted Zyprexa for various uses that are allegedly "off-label" and

[5] Although other federal courts have recently declined to exercise removal jurisdiction in Zyprexa-related false claims suits, those cases are all distinguishable because, unlike Plaintiffs' allegations herein, the plaintiffs in those cases did not allege violations of the *federal* False Claims Act. *See Alaska v. Eli Lilly & Co.*, 2006 WL 2168831 (D. Alaska July 28, 2006); *Utah. v. Eli Lilly & Co.*, 2007 WL 2482397 (D. Utah Sept. 4, 2007); *South Carolina v. Eli Lilly & Co.*, 2007 WL 2261693 (D. S.C. Aug. 3, 2007). The Utah decision is further distinguishable because, unlike in this case, there were independent state-law bases for deciding plaintiff's state False Claims Act claims, which relied on state-law definitions of, for example, "medically necessary." *See, e.g., Utah*, 2007 WL 2482397 at *4 (noting that plaintiff's claims were based in part on two provisions of Utah law and concluding that "[g]iven these multiple bases, resolution of [the state false claims act cause of action] does not hinge solely on a federal question.") Here, however, the Complaint does not allege any cognizable standard of California law as a basis for its claims under the California False Claims Act. Rather, resolution of Counts I and II will turn entirely on disputed and substantial federal questions. *See*, ¶¶ 17-37.

not "medically accepted indications," both concepts defined according to federal law, thereby causing harm to California.[6] For example, the Complaint alleges that by illegally marketing Zyprexa for off-label uses, Lilly caused physicians and pharmacies to request Medicaid reimbursement for uses for which Zyprexa was not eligible under the Medicaid Program. Compl. ¶¶ 49-50. The same basic allegations were made by the States of Louisiana, West Virginia and Mississippi against Lilly with respect to Zyprexa. *See In re Zyprexa Prods. Liab. Litig.*, 375 F. Supp. 2d 170 (E.D.N.Y. 2005); *West Virginia v. Eli Lilly and Company*, 476 F. Supp. 2d 230 (E.D.N.Y. 2007); *Hood v. Eli Lilly and Company*, 2007 WL 1601482 (E.D.N.Y. June 5, 2007). Lilly disputes these allegations, including specifically the allegation that it violated the FDCA by marketing the drugs for uses that are not medically necessary or indications that are not medically accepted.

24. As a currently marketed prescription drug, Zyprexa is subject to extensive regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(8), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The Commissioner of the FDA has the authority to promulgate regulations to enforce the FDCA, which are codified in the *Code of Federal Regulations*, 21 C.F.R. § 1, *et seq.* *See* 21 U.S.C. § 371(a).

25. Promotional claims to physicians about Zyprexa are regulated by the FDA to ensure that the claims are in compliance with the FDCA and FDA implementing regulations. Of particular relevance, the FDA reviews promotional materials to assure that they do not create new "intended uses" for which adequate directions are, in the absence of FDA approval of the drug for that use, lacking, thereby violating Section 502(f)(1) of the FDCA, 21 U.S.C. § 352(f)(1). The FDA also reviews promotional labeling to assure that it does not recommend or suggest conditions of use that would make the drug an "unapproved new drug" under section 505(a), 21 U.S.C. § 355(a), the distribution of which in interstate commerce would violate federal law. Detailed regulations

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[6] Promotion for non-FDA approved uses is "a promotion that violates the [FDA's] strictures on off-label marketing." *United States ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert Co.*, 2003 WL 22048255, at *2 (D. Mass. Aug. 22, 2003).

implementing these general provisions, as well as a general statutory prohibition against labeling that is false or misleading "in any particular," appear in 21 C.F.R. § 201 and 202. *See also* 21 C.F.R. §§ 310 and 314 ("new drug" and "new drug" approval requirements).

26. As an integral part of this comprehensive statutory and regulatory scheme governing the content of promotional claims, the FDA has crafted a number of rules and policies expressly allowing manufacturers to engage in the non-promotional dissemination of information to physicians about new drugs and new uses of approved drugs. FDA regulations expressly permit scientific exchange by manufacturers and their representatives about investigational new drugs and investigational uses of approved new drugs. *See* 21 C.F.R. 312.7(a). The FDA has also recognized that manufacturer dissemination of scientific information – through reprints of medical journal articles, support of CME, and responses to unsolicited requests for information – is not only allowed but entirely appropriate and, indeed, a necessary corollary of the agency's long-standing policy of non-interference in physician decisions to prescribe approved drugs off-label as part of medical practice. *See, e.g.*, 59 Fed. Reg. 59,820, 59,823 (Nov. 18, 1994) ("The agency has recognized the need among health care professionals for peer review and dissemination of the latest significant scientific data and information on drugs an devices in scientific journals."); 21 C.F.R. § 312.7 (pre-approval promotion ban "is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media."). Taken together, the content regulatory provisions of the FDCA and FDA regulations describe above, and the various policies established by FDA to facilitate scientific exchange about off-label uses, comprise a careful federal system balancing the scientific informational needs of physicians and the public interest in assuring that commercial communications are truthful and non-misleading. And above and beyond this, the courts have made clear that another source of federal law – the Constitution – limits the government's ability to restrict the dissemination of truthful non-misleading information concerning their products. *See, e.g., Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), vacated on other grounds, *Washington Legal Found. v. Henney*, 128 F. Supp.

2d 11 (D.D.C. 2000). Allegations regarding any specific communication must be resolved with reference to this carefully balanced complex of *federal* law.

27. The FDA's responsibility to regulate prescription drugs sold in the United States, and to enforce laws with respect to such drugs, inclusive of the precise content and format of prescription drug labeling (*e.g.*, the instructions, warning, precautions, adverse reaction information provided by manufacturers, and marketing materials), is plenary and exclusive. *See* 21 U.S.C. § 301, *et seq.*

28. Plaintiffs have made alleged violations of federal law a critical element of one or more of its claims against Lilly. Accordingly, Plaintiffs' claims regarding the safety, labeling, promotion and marketing of Zyprexa necessarily raise substantial federal questions by requiring the Court to interpret the meaning of the FDCA and its implementing regulations.

2. Plaintiffs' Right to Relief Requires Resolution of Disputed and Substantial Issues Under the AKS

29. Plaintiffs' False Claims Act claims also require resolution of disputed and substantial issues under the federal AKS because they require resolution of whether specific items of remuneration allegedly paid by Lilly would constitute a violation of the federal kick-back prohibitions. For example, while Plaintiffs allege at paragraph 198 of the Complaint that Lilly allegedly paid kick-backs in the form of "speaker fees,' honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa," Plaintiffs elsewhere acknowledge (Compl. ¶ 200, p. 40), as they must, that not every payment made to a physician violates AKS. To the contrary, the federal AKS only prohibits payments meant to "induce" the recipient (1) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (2) to purchase or lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program. Compl. ¶ 192 (quoting 42 U.S.C. § 1320a-7b(b)(2)(A) & (B)).

30. Although Plaintiffs conclude that such remuneration was, in fact, paid, thereby resulting in false claims being filed with the government, Plaintiffs cannot dispute (and indeed

allege) that at least the stated purposes of those payments were legitimate, including speaker fees, honoraria, and educational grants. Compl. ¶ 198 (p. 40, 42) (alleging that "Lilly paid, and physicians accepted, cash payments thinly-veiled as 'speaker fees,' honoraria, and . . . educational grants"). Calling them "thinly-veiled," however, only begs the question. In each instance, Plaintiffs must prove and the Court examine the individual circumstances of the payment and services provided to determine if there was a violation of the AKS. Furthermore, there are statutory exceptions and regulatory safe harbors under the federal AKS that expressly protect certain payments, including payments provided by pharmaceutical manufacturers to both physician and non-physician service providers, that comply with the safe harbor requirements. Indeed, depending on the circumstances of the payments and the services provided, the personal services safe harbor, 42 C.F.R. § 1001.952(d), may in fact insulate as a matter of law many of the payments Plaintiffs allege were improper. Determination of the alleged impropriety of these payments thus involves an analysis of complex *federal* statutes and regulations.

31. California's Health & Safety Code §§ 119400-02 (also cited by Plaintiffs) does not provide an alternative and independent state law basis for imposing False Claims Act liability. Unlike the AKS, the California statutes do not impose any substantive limits on remuneration to health care providers; rather, as Plaintiffs' allegations make clear, they merely require manufacturers to establish compliance programs which implement a self-imposed and self-defined "'specific annual dollar limit on gifts, promotional materials, or items or activities" that the manufacturer may provide to medical or health care professionals.'" Compl. ¶ 206 (p. 41) (quoting Calif. Health & Safety Code § 119402(c)-(d)). Plaintiffs do not allege that Lilly failed to adopt such a compliance policy or failed to adhere to the policy it adopted. Moreover, nothing in that compliance policy is in any way tied to a claim for reimbursement, which is, of course, a necessary element for liability under the California False Claims Act.

3. Plaintiffs' Right to Relief Requires Resolution of Disputed and Substantial Issues Under Federal Medicaid Law

32. Plaintiffs' claims also raise disputed and substantial questions of federal law under the Social Security Act because they depend upon the interpretation and application of federal statutory provisions governing a State's reimbursement for prescription medicines. Plaintiffs' Complaint admits as much. *See* Compl. ¶ 37 (alleging that "[f]ederal statutes and regulations restrict the drugs and drug uses that the federal and state governments will pay for Medicaid programs."). In particular, the Complaint alleges that, under federal law, reimbursement of Medicaid claims is limited to "covered outpatient drug[s]," defined as "those drug[s] prescribed to treat medically excepted [sic] indications." Compl. ¶ 39 (citing 42 U.S.C. § 1396(k)(3). According to the Complaint, federal law further defines a "medically accepted indication" as "any use approved by the FDA, or supported by one of the three specifically identified compendia." Compl. ¶ 39 (citing 42 U.S.C.A. § 1396(k)(6)).

33. These federal definitions and rules are indispensable to Plaintiffs' state law causes of action for violation of the California False Claims Act. For example, Plaintiffs allege that "[w]hether the use of a drug is medically necessary was material to Medicaid's decision to reimburse for prescription" (Compl. ¶ 42), however, "[u]se of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, and therefore should not have been covered by the State of California's Medicaid programs." Compl. ¶¶ 42-43.

34. The federal Medicaid program authorizes federal grants to states to provide medical assistance to low income individuals. 42 U.S.C. § 1396, *et seq.* "Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services." *Wilder v. Virginia Hosp. Ass'n*, 496 U.S. 498, 502 (1990).

35. Federal law requires the States, subject to certain narrow exceptions, to reimburse FDA-approved prescription drugs of any manufacturer that has entered into and complies with a

rebate agreement with the Secretary of Health and Human Services, 42 U.S.C. § 1396r-8(d)(4)(B). Thus, California is required under federal law to reimburse for drugs, such as Zyprexa, if the manufacturer complies with federal requirements.

36. The only time a state can exclude from its formulary (or preferred drug list) a covered outpatient drug subject to a rebate agreement is "with respect to the treatment of a specific disease or condition for an identified population . . . if, based on the drug's labeling . . . the excluded drug does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion." 42 U.S.C. § 1396r-8(d)(4)(D). Moreover, even a decision to require prior authorization must satisfy federally-mandated requirements. 42 U.S.C. §§ 1396r-8(d)(4)(E), (d)(5). Thus, every step a state takes with regard to Medicaid coverage of an FDA-approved drug is subject to strict federal mandates.

4. The Federal Interest in Providing a Forum

37. The federal government has a strong interest in having a federal court decide several of the issues in this case. Among these issues are (1) whether any conduct of Lilly, including the alleged marketing of Zyprexa for unapproved or non-medically necessary uses, violated any federal laws or regulations related to the labeling and marketing of drugs; (2) whether Lilly's alleged dissemination of information about such uses was protected by the First Amendment of the United States Constitution; (3) whether the federal AKS prohibited certain payments made by Lilly to physicians for, *inter alia*, speaker fees, honoraria, and educational grants; and (4) whether federal Medicaid law permitted reimbursement for the uses in which Zyprexa was prescribed.

38. Plaintiffs' claims may be vindicated or defeated only by construction of federal statutes and regulations. The availability of a federal forum to protect the important federal interests at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314.

* * * * *

WHEREFORE, Lilly notices the removal of this case to the United States District Court for the Northern District of California pursuant to 28 U.S.C. §§ 1331, 1367, & 1441, et seq.

Dated: September 21, 2007

SIDLEY AUSTIN LLP

By: _____
Geoffrey M. Edgar

Attorneys For Defendant
ELI LILLY AND COMPANY

PROOF OF SERVICE

I am employed in the County of San Francisco, State of California. I am over the age of 18 and not a party to the within action. My business address is Sidley Austin LLP, 555 California Street, San Francisco, California 94104.

On September 21 , 2007, I served the foregoing document(s) described as **NOTICE OF REMOVAL** on all interested parties in this action as follows (or as on the attached service list):

☒ (U.S. MAIL) I served the foregoing document(s) by U.S. Mail, as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's business practice for collection and processing of correspondence for mailing. Under that practice, the correspondence would be deposited in the United States Postal Service on that same day in the ordinary course of business, with postage thereon fully prepaid.

☐ (U.S. EXPRESS MAIL) I served the foregoing document(s) by Express Mail, as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's practice for collection and processing of correspondence for mailing via Express Mail. Under that practice, the Express Mail would be deposited in the United States Postal Service on that same day in the ordinary course of business, with Express Mail postage thereon fully prepaid.

☐ (FACSIMILE) I caused the foregoing document(s) to be served by facsimile transmission from facsimile machine number (415) 772-7400 to the interested party at the facsimile telephone numbers shown. Each transmission was reported as complete and without error. A transmission report was properly issued by the sending facsimile machine for each interested party served.

☐ (FEDERAL EXPRESS) I served the foregoing document(s) by Federal Express as follows: I placed true copies of the document(s) in a sealed envelope addressed to each interested party as shown above. I placed each such envelope for collection and mailing at Sidley Austin LLP, San Francisco, California. I am readily familiar with the Firm's practice for collection and processing of correspondence for mailing via Federal Express (an express service carrier which provides overnight delivery). Under that practice, the sealed, addressed envelope(s) are delivered to an authorized courier or driver authorized by Federal Express the same date they are collected and processed, with all charges paid.

☐ (HAND DELIVERY) I caused the document(s) to be delivered by hand by a courier service to the addressee(s) shown above unless otherwise noted.

☐ (E-MAIL) I caused the document(s) to be delivered by e-mail to each interested party as shown above.

☐ (LEXIS NEXIS) I caused the document(s) to be delivered by e-mail by Lexis Nexis File & Serve to each interested party as shown above.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on September 21, 2007, at San Francisco, California.

By: Gabriela Rodriguez

Gabriela Rodriguez

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